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510(k) Summary
Linvatec Biomaterials
SmartPin

Submitter's Name, Address, Telephone Number, and Contact Person

Linvatec Biomaterials Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5600
Facsimile: 358-3-316 5629

Date prepared: March 9, 2004

Name of the device:

A.	Trade or Proprietary Name:	SmartPin
B.	Common Name:	Bioabsorbable bone fixation pin
C.	Classification Name:	Bone Fixation Pin
D.	Device Product Code:	class II, HTY

Predicate Device:

1. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartPin® (the previous PLLA Pin) (K010983),
2. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartPin® PDX (the previous PLGA Pin) (K003659),
3. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) Biofix SR-PGA Pin (K890902),
4. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartNail® (K993074, K031981)

Intended Use:

SmartPin® is indicated for fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments in the presence of appropriate immobilization.

Device Description:

The device description of SmartPin® is as follows:

- Composed of poly-96L/4D-lactide copolymer
- Tapered, smooth pins
- Lengths 10 - 70mm
- Diameters 1.1, 1.5, 2.0, 3.2 and 4.5 mm

The dimensions and shape are completely identical with Linvatec Biomaterials SmartPin® (the previous PLLA Pin) (K010983), SmartPin® PDX (the previous PLGA Pin) (K003659) and Biofix SR-PGA Pin (K890902).

Substantial Equivalence:

SmartPin® made of poly-96L/4D-lactide copolymer owns the following similarities to cleared devices SmartPin® (the previous PLLA Pin) (K010983), SmartPin® PDX (the previous PLGA Pin) (K003659) and Biofix SR-PGA Pin (K890902):

- has the same or similar indicated use
- use the same operating principle
- incorporate the same basic design
- is manufactured by same machinery
- is packaged and sterilized using the same materials and processes

In summary, SmartPin® described in this notification is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Linvatec Biomaterials Ltd.
P.O. Box 3
Hermiankatu 6-8 L
FIN 33721
Tampere, Finland

Re: K041288
Trade/Device Name: SmartPin®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: March 15, 2004
Received: May 13, 2004

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K041288

Device Name: SmartPin®

Indications for Use:

SmartPin® is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

SmartPin® is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) treatment of physeal fractures in children, because the effect of SmartPin® upon the healing of growth plate has not been tested clinically.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041288